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EXAMINER

TRAN, SUSAN T

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Response to Arguments

Applicant's arguments filed 03/07/08 have been fully considered but they are not persuasive.

Applicant argues that in contrast to the present invention, Nara teaches a coating composition that comprises a water insoluble polymer and a swellable polymer, while the present claimed coating semipermeable layer comprises a single polymer. Applicant further argues that the intermediate layer taught by Nara which contains a single polymer, but does not contain a modifying agent.

However, applicant's arguments are not persuasive for the following reasons:

1) it is noted that the coating composition of the present invention also comprises a swellable polymer such as those taught by Nara. The only difference is that the swellable polymer and the water insoluble polymer of the present invention are coated onto the core in 2 separate steps (see examples 2 and 3 at pages 12-13 of the present specification), while the swellable polymer and the water insoluble polymer taught by Nara are combined and then coated onto the core in one single step. Nara teaches an omeprazole composition that is capable of releasing active drug at higher rates in the intestine tract than in the stomach to maintain an almost constant plasma concentration of drug and ensure effect of drug in the body for an extended period of time (column 1, lines 51-57). Accordingly, the examiner is unable to determine the unexpected result of an omeprazole core coated with a water insoluble polymer and a swellable polymer in two separate coating layers, over the coating of the same ingredients in a single coating solution; and

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2) if the intermediate coating layer of Nara is relied upon, although Nara is silent as to the use of modifying agent in the intermediate layer, Nara is cited in combination with Bergstrand for the teaching of adding modifying agent to an intermediate coating layer is well known in the art, much less to an intermediate coating layer of the same drug, *e.g.*, omeprazole. It is noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

/S. Tran/
Primary Examiner
Art Unit 1618